UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,295	10/31/2003	Se Ho Park	123034-05004796	8427

43569 7590 07/12/2006

MAYER, BROWN, ROWE & MAW LLP
1909 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER	
CALAMITA, HEATHER	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,295	PARK ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Claims 1-7 are currently pending and under examination. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Objections

2. Claim 6 is objected to because of the following informalities: In claim 6 lines 6-7, the recitation of "said extension time increases by value [(Lmax - Lmin) / (rate of DNA synthesis of taq DNA polymerase; bp/sec)] /(number of total cycles - 7) per cycle, uses square brackets. This is confusing as the use of square brackets in the claims indicates a deletion of claim language. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "said diluted samples" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim because claim 7 depends from claim 2 and the limitation for dilution of the samples appears for the first time in dependant claim 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Khaled et al. (FEMS Microbiology Letters, 1997).

With regard to claim 1, Khaled et al. teach a method for performing multiplex PCR for having at lest two amplified DNA products from samples positioned within a PCR equipment, characterized in that the primer annealing temperature and extension time are changed by a constant amount per constant number of cycles (see p. 193 paragraph 2.3 and table 2, where multiple primers are used to produce multiple DNA products. Khaled et al. teach raising the annealing temperature from 40^0C to 50^0C and changing the extension time from 30 seconds to 8 minutes).

With regard to claim 2, Khaled et al. teach the samples are genomic DNA (see p. 192 paragraph 2.2, where the total genomic DNA was extracted from the bacteria and used as a template).

With regard to claim 4, Khaled et al. teach the PCR equipment can change primer annealing temperature and extension time are changed by a constant amount per constant number of cycles (see p. 193 paragraph 2.3, where Khaled discloses the use of FTS-1 thermal sequencer).

With regard to claim 5, Khaled et al. teach the annealing temperature and extension time increase by a constant amount per constant number of cycles (see p. 193 paragraph 2.3 and table 2, where multiple primers are used to produce multiple DNA products. Khaled et al. teach raising the annealing temperature from 40^0C to 50^0C and changing the extension time from 30 seconds to 8 minutes).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaled et al. (FEMS Microbiology Letters, 1997) in view of Burckhardt (USPN 5,501,963, March 1996).

The teachings of Khaled et al. are described previously.

Khaled et al. do not teach diluted blood or a sample volume of less than a microliter.

With regard to claims 3 and 7, Burckhardt teaches diluted blood and a sample volume of less than a microliter (see col. 16 line 4 and table 4, where the blood sample was diluted to various concentrations).

One of ordinary skill in the art at the time the invention was made would have been motivated to dilute the sample as taught by Burckhardt with the method of PCR as taught by Khaled in order to conserve the sample for future applications. Burckhardt teaches one microliter of whole blood is sufficient for amplification (see col. 16 line 4). It would have been prima facie obvious to use a small sample volume as taught by Burckhardt with the method of PCR as taught by Khaled in order to conserve sample for use in future applications or analysis.

Allowable Subject Matter

6. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicants' arguments with respect to the rejections over Khaled have been fully considered but they are not persuasive.

Applicants argue Khaled states the annealing temperature was raised to 50^0C but does not disclose in what manner the temperature is increased and that Khaled does not disclose or teach changing the primer annealing temperature by a "constant amount per constant number of cycles. This argument is

not persuasive because Khaled teaches an increase in annealing temperature of 10^0C, a constant amount, over a constant number of cycles, specifically, one cycle and alternatively, over X cycles as well since the claim requires only a constant number of cycles.

Applicants additionally argue Khaled does not disclose or teach changing the extension time, let alone changing the extension time by a "constant amount per constant number of cycles." Applicants note Khaled discloses a final extension time of 8 minutes but Applicants assert this is not the cyclical extension step to which claim 1 refers. The extension time of claim 1 refers to the extension time during the PCR cycles and not the final extension step. These arguments are not persuasive because Khaled teach changing the extension time "a constant amount over a constant number of cycles" Khaled changes the extension time from 60 seconds to 8 minutes over one cycle. The change in extension time is constant, specifically, 7 minutes and the number of cycles is constant, specifically 1. Khaled, therefore meets the limitation of claim 1.

Applicants argue, with respect to claims 2, 4 and 5 Khaled do not teach the primer annealing temperature and extension time are changed by a constant amount per constant number of cycles. This argument is not persuasive for the reasons stated above.

Applicants' arguments with respect to the rejections over Khaled and Burckhardt have been fully considered but they are moot in view of the clarification of the application of Khaled.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

hgc

TERESA E. STRZELECKA, PH.D.
PRIMARY EXAMINER

Teresa Strzelecka
7/7/06